November 24, 2021

Health & Life Co., Ltd
Melody Jiang
Regulatory Affairs
9F, No. 186, Jian Yi Road Zhonghe District
New Taipei, 23553
Taiwan

Re: K211744
Trade/Device Name: Non-Contact Infrared Thermometer, model HL710H
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 28, 2021
Received: November 2, 2021

Dear Melody Jiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211744

Device Name
Non-Contact Infrared Thermometer, model HL710H

Indications for Use *(Describe)*
The Non-Contact Infrared Thermometer, model HL710H is intend for the measurement of human body temperature from the forehead. The device is indicated for use by people of all ages in the home.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PREMARKET NOTIFICATION

K211744 - 510(k) SUMMARY

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date: NOV 24 2021

1. Submitter:

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2. Name of the Device:

Trade Name: Non-Contact Infrared Thermometer, model HL710H
Common Name: Clinical electronic thermometer
Regulation Name: Clinical electronic thermometer
Classification: Class II
Regulation: 21 CFR 880.2910
Classification Panel: 880 General Hospital and Personal Use Devices
Product Code: FLL

3. Information for the 510(k) Cleared Device (Predicate Device):

Microlife Non-Contact Infrared Forehead Thermometer, Model: FR1DG1(NC200)
(K191829)

4. Device Description:

The Non-Contact Infrared Forehead Thermometer, Model HL710H is an electronic thermometer using an infrared sensor which can put out different signal when measuring different object temperature or in different ambient temperature to measure infrared energy radiated from the forehead. This energy is collected through the Infrared sensor and converted to a temperature value, then display it by LCD.

The subject device HL710H features a Bluetooth transmission function, which enables the device transmit measured results to paired Bluetooth-enabled device after measurement.

When Bluetooth transmission connection established, the device would transmit measured temperature results with time to the Bluetooth enabled device. Before attempting to sync the thermometer with your Bluetooth enabled device, make sure Bluetooth function is turned ON in both your Bluetooth enabled device and the thermometer.

Additional, HL710H has some feature as below:

High Temperature Notice

HL710H has a built-in "High Temperature Notice" feature.

To user who have a high temperature between 37.5 ~ 43.0 °C (99.5 °F ~ 109.4 °F), "High Temperature Notice" function will inform them with: Flashing result, red LED backlight, and a series of 'beep' sound.

5. Indications for Use

The Non-Contact Infrared Thermometer, model HL710H is intend for the measurement of human body temperature from the forehead. The device is indicated for use by people of all ages in the home.

6. Substantial Equivalence Comparison:

Product Specification Comparison Table of Subject Device HL710H, and Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) (K191829)

Comparison Items	**Subject Device Non-Contact Infrared Thermometer HL710H**	**Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) K191829**	**Results**
Indications for use	The Non-Contact Infrared Thermometer, model HL710H is intend for the measurement of human body temperature from the forehead. The device is indicated for use by people of all ages in home.	The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200) is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home.	same
Thermometer type	Infrared thermometer	Infrared thermometer	same
	Non-Contact	Non-Contact	
Device Measurement Technology	Infrared	Infrared	same
Temperature Measurement distance	Appropriate within 5 cm	Appropriate within 5 cm	same
Measuring Location (human)	Forehead	Forehead	same
Mode of operation(Body temperature)	Adjusted mode	Adjusted mode	same

Appearance			Different
Physical dimension	147 mm x 37 mm x 34 mm	156.7 x 43 x 47 mm	Different
Weight	62.1g±10g (2.44 g ± 0.35 oz) (Battery Excluded)	68.5 g (without batteries)	Similar
Power supply	3.0V DC with 2 AAA 1.5V alkaline batteries	3.0V DC with 2 AAA batteries	same
Display resolution	0.1°C or 0.1°F	0.1°C or 0.1°F	same
Measuring range	22.0 °C ~ 43.0 ˚C (71.6 °F~ 109.4 °F)	32.0-43.0 °C (89.6~109.4 °F)	Different
Accuracy	±0.2 °C: 35.0 ~ 42.0 °C; ±0.3 °C: 22.0 ~ 33.9 °C, 34.0 ~ 34.9 °C, 42.1 ~ 43.0 °C; ±0.4 °F: 95.0 ~ 107.6 °F; ±0.5 °F: 71.6~93.0 °F, 93.2 ~94.8 °F; 107.8~109.4 °F	±0.2 °C: 35.0 ~ 42.0 °C; ±0.3 °C: 34.0 ~ 34.9 °C; 42.1 ~ 43.0 °C; ±0.4 °F: 95.0 ~ 107.6 °F; ±0.5 °F: 93.2 ~94.8 °F; 107.8~109.4 °F	Different
Operating Conditions (Body)	10 °C~40 °C(50.0 °F~104.0 °F), 15%~95 % R.H.	15~40°C (59°F~104°F), 15~95 % R.H.	Different
Storage conditions	-20.0 °C ~ 70.0 °C (-4.0 °F ~ 131.0 °F)≦95 % R.H.	-25 ~ 55 °C(-13°F ~131°F) 15-95 % relative maximum humidity	Different
Display type	LCD display	LCD display	same

Memory	12 sets memories	30 sets memories	Different
Measurement time	1-2 seconds	3 seconds	Different
Error	Error Symbol.  System error. Please return the device to local distributor.	Display  or  when system has a malfunction	Different
Patient-Contact Button material	ABS	PMMA	Different
Housing and battery cover material	ABS	ABS	Same
Probe cover	-	-	none
Sensor type	Thermopile	Thermopile	Same
reference body site	Oral	Oral	Same
Backlight	Green and red backlight according to the measured temperature	Green and red backlight according to the measured temperature	Same
Biocompatibility	Cytotoxicity: ISO 10993-5:2009 Sensitization: ISO 10993-10: 2010 Irritation or intracutaneous reactivity: ISO 10993-10: 2010	Change in Material same as K183663 (Microlife Digital Infrared Ear Thermometer, Model IR1 DN1 (IR210))	Same

For those differences, we did the relevant evaluations to demonstrate that those differences don't affect the safety and performance of subject device HL710H. The detail discussions are as follows,

1) Materials and Physical Composition

Both the predicate device FR1DG1 (NC200) (K191829) and the subject device HL710H's sensor, microprocessor, LCD are using same materials.

The body-contacting part of the subject device HL710H passed biocompatibility evaluations and shows that the subject device complies with standards ISO 10993-1, ISO 10993-5, and ISO 10993-10. Thus, this difference does not raise any new safety or performance questions.

2) Energy Source

Both the predicate device FR1DG1 (NC200) and the subject device HL710H obtain its energy from 2 AAA (1.5V, LR03) Alkaline Batteries. Besides, the subject device HL710H passed EMC and Electrical Safety validations as well as predicate device FR1DG1 (NC200) (K191829). Therefore, there are no issues associated with energy source relevant to this analysis. This has been tested and confirmed according to IEC 60601-1-2: 2014; IEC 60601-1, AAMI/ANSI ES60601-1: 2005/(R2012).

3) Appearance and Physical Dimension

The physical dimension of the subject device Non-Contact Infrared Thermometer HL710H is 147 x 37 x 34mm, while predicate device FR1DG1 (NC200) is 156.7 x 43 x 47 mm. The difference is caused because of their different appearance, but these difference does not raise any new safety and effectiveness questions. This has been tested and confirmed according to IEC 60601-1-2: 2014; IEC 60601-1, AAMI/ANSI ES60601-1: 2005/(R2012) and ISO 80601-2-56 Second edition 2017-03.

4) Weight

The weight of the subject device Non-Contact Infrared Thermometer HL710H is 62.1g±10g, while predicate device FR1DG1 (NC200) is 68.5 g. The weight is similar around 62-69 g, this is because of their different appearance, people feel same when holding the product. The difference does not raise any new safety and effectiveness questions.

5) Measurement range

The subject device HL710H body mode measurement range is 22.0 °C ~ 43.0 °C(71.6 °F ~ 109.4 °F), whereas the predicate device FR1DG1 (NC200) measurement range is 32.0-43.0 °C (89.6~109.4 °F). Despite minor differences in the

measurement ranges between the subject and predicate device, these are within the ISO 80601-2-56 Second edition 2017-03 and ASTM E1965-98(Reapproved 2016) requirements, and therefore, meet this performance standard. This does not introduce any new risk to the device.

6) Accuracy

The subject device HL710H and the predicate device FR1DG1 (NC200) can both measure human body's temperature, it does not have significant difference of performance. The subject device HL710H extended the temperature as ±0.3 °C: 22.0 ~ 33.9 °C; ±0.5 °F: 71.6~93.0 °F, wider than the predicate device. Moreover, HL710H's accuracy is inclusive of the predicate's accuracy; this difference has been verified in compliance with the standard. The difference does not affect the performance and accuracy which was evaluated in the performance testing.

7) Operating conditions

The operating temperature range of subject device HL710H body mode is 10 °C~40 °C(50 °F~104.0 °F), 15%~95 % R.H, whereas he temperature range of predicate device FR1DG1 (NC200) is 15~40°C (59°F~104°F), 15~95 % R.H. these are within the IEC 60601-1-11: 2015, ISO 80601-2-56 Second edition 2017-03 and ASTM E1965-98 (Reapproved 2016) requirements, and therefore, meet these performance standards. The difference does not affect the performance and accuracy which was evaluated in the performance testing.

8) Storage conditions

The storage temperature range of subject device HL710H is -20.0 °C ~ 55.0 °C (-4.0 ˚F ~ 131.0 ˚F) with ≦95 % R.H., whereas storage temperature range of the predicate device FR1DG1 (NC200) is -25 ~ 55 ˚C (-13˚F ~131˚F) with 15-95 % relative maximum humidity. Despite minor differences in the storage environment between the subject and predicate device, these are within the IEC 60601-1-11: 2015, ISO 80601-2-56 Second edition 2017-03 and ASTM E1965-98(Reapproved 2016) requirements, and therefore, meet these performance standards. The difference does not affect the performance and accuracy which was evaluated in the performance testing.

9) Memory

The memory of subject device HL710H is 12 sets memories, whereas the memory of predicate device FR1DG1 (NC200) is 30 sets memories.
The "Memory" and "Operating condition" of subject device is similar with predicate device, the software verification and validation test met the requirements. The performance testing shows that the subject device complies with performance standard. Thus, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

10) Measurement time

The measurement time of subject device HL710H is 1-2 seconds, whereas the measurement time of predicate device FR1DG1 (NC200) is 3 seconds.
Both of HL710H and FR1DG1 (NC200) measure temperature in a short time, no more than 3 seconds.

11) Error

Both subject device HL710H and the predicate device FR1DG1 (NC200)(K191829) have a self-test function. The principle of the self-test is the same. Devices can perform a self-test every time when it is switched on to always guarantee the specified accuracy of any measurement, when it has error, it will display signal. HL710H device will display icon "ErC", FR1DG1(NC200) will display icon "Er0" or "Er6". Although the icons are different, but the purpose is the same. It does not affect the device's performance, safety or effectiveness.

12) Patient-Contact Button material

The Patient-Contact Button material of HL710H is ABS (PA757), the Patient-Contact Button material of FR1DG1 (NC200) is PMMA.
The body-contacting part of the subject device HL710H passed biocompatibility evaluations with reports, shows that the subject device complies with standards ISO 10993-1 Fifth edition (2018-08), ISO 10993-5 Third edition (2009-06-01), and ISO 10993-10 Third Edition (2010-08-01). Thus, this difference does not raise any new safety or performance questions.

7. Discussion of Clinical Tests Performed:

The subject device HL710H is compliant to the standard of ISO 80601-2-56:2017 (Particular requirements for basic safety and essential performance of clinical

thermometers for body temperature measurement) and ASTM E1965-98:2016 (Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature) to validate the clinical accuracy of IR thermometer. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

The subject device was tested to evaluate its safety and effectiveness, including the following:

EMC/Electrical Safety:

- ANSI/AAMI ES60601-1:2005/(R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012: Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015: Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-2: 2014: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Performance:

- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
- ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement [Including: Amendment 1 (2018)]

Risk Management:

- ISO 14971: 2007, Medical devices -- Application of risk management to medical devices

Software Design and Development:

- IEC 62304: 2006/A1:2016 Medical device software - Software life cycle

processes [Including Amendment 1 (2016)]

Biocompatibility:

- ISO 10993-1 Fifth edition (2018-08), Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Third edition (2009-06-01) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition (2010-08-01) Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

FCC Test:

- FCC 47 CFR Part 15, Subpart B, C

9. Conclusions:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject device was tested and fulfilled the requirements of the standards mentioned above. The Non-Contact Infrared Thermometer, model HL710H is substantially equivalent to the Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) cleared under K191829 with respect to the indications for use and technological characteristics.